

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Sarah Smith on 11 June 2010.

The application has been amended as follows:

1. A method of preparing a protein coaggregate, ~~which method comprises~~esting the acidification of an aqueous protein solution ~~of the protein~~ having a first and a second protein,

wherein the pH of the solution lies above the isoelectric point of both of the proteins,

wherein ~~[[a]]~~ said first protein, which through acidification is able to form a protein aggregate, is acidified in the presence of a second protein in the aqueous solution in order to form a coaggregate comprising the first and second protein,

and wherein, under identical temperature conditions and pH, the second protein does not form a protein aggregate in the absence of the first protein.

2. ~~[[A]]~~ The method according to claim 1, wherein the first protein is obtained from a first source~~[[,]]~~ and the second protein is obtained from a second source.

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3. (Currently amended) ~~[[A]]~~ The method according to claim 1, wherein acidification occurs by placing the aqueous protein solution under a CO<sub>2</sub> atmosphere, wherein under identical conditions of temperature, concentration and pressure, the second protein does not form a protein aggregate in the absence of the first protein.

4. (Currently amended) ~~[[A]]~~ The method according to claim 3, wherein the CO<sub>2</sub> pressure is raised within 10 seconds to the highest value.

5. (Currently amended) ~~[[A]]~~ The method according to claim 1 further comprising stabilizing the ~~wherein the formed coaggregates are stabilised with the aid of~~ through the addition of a cross-linker.

6. (Currently amended) ~~[[A]]~~ The method according to claim 1, wherein the second protein used is a pharmacologically active protein.

7. (Currently amended) ~~[[A]]~~ The method according to claim ~~[[4]]~~ 3, wherein the formation of the protein coaggregate ~~with the aid of~~ by acidification with CO<sub>2</sub> ~~occurs~~ while further comprising stirring the solution.

- Cancel claim 8.

## REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: the claims are drawn to a method of A method of preparing a protein coaggregate, comprising the acidification of an aqueous protein solution having a first and a second protein, wherein the pH of the solution lies above the isoelectric point of both of the proteins,

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wherein said first protein, which through acidification is able to form a protein aggregate, is acidified in the presence of a second protein in the aqueous solution in order to form a co-aggregate comprising the first and second protein, and wherein, under identical temperature conditions and pH, the second protein does not form a protein aggregate in the absence of the first protein. While the method of isoelectric precipitation of proteins by acidification, and specifically when using CO<sub>2</sub> as the volatile acid, is well known in the art (see, for example, Hofland et al. cited on the instant IDS) the method has been used solely for precipitation of a single protein. However, it is both novel and unexpected that said method could be utilized to co-aggregate or co-precipitate a second protein which is resistant to aggregation or precipitation wherein the first protein traps, or forms a biodegradable matrix, around said second protein. As such, the instant methods are both novel and non-obvious and **claims 1-7 are allowed**.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/  
Primary Examiner, Art Unit 1656  
11 June 2010